THE CANCER LETTER INTERACTIVE

Vol. 27 No. 43
Nov. 23, 2001

Price $295 Per Year

PO Box 9905 Washington DC 20016 Telephone 202-362-1809

Advisors Approve Lung Screening Trial Testing Spiral CT Vs. X-Ray, For $200M

NCI advisors approved the Institute's plan to commit nearly $200 million over the next eight years to test whether a new lung cancer screening method, spiral CT scanning, can detect lung cancers early enough to reduce mortality from the disease.

The NCI Board of Scientific Advisors last week voted 17-8 in favor of the Institute's rewritten proposal for the study. Last June, the board in a tie vote did not approve an earlier design for the trial, which would have cost $52 million (**The Cancer Letter**, June 29, Vol. 27 No. 26).

The new study will be about four times more expensive than the

(Continued to page 2)

In Brief:

Cure for Lymphoma Foundation Awards Five; Lefall Honored; AACR Begins New Journal

CURE FOR LYMPHOMA FOUNDATION presented five awards at its annual Cabaret for the Cure on Oct. 29 in New York. **Mathew Broderick**, stage and film actor, received the Honorary Chair award for fund raising; **Richard Klausner**, former director of NCI, was given the Key to the Cure award for his leadership in the development of the lymphochip and the convening of a Progress Review Group to establish research priorities for lymphoma and other blood cancers; **David Robinson**, president, chairman and CEO of Ligand Pharmaceutical Inc., received the Trailblazer award for products approved for cutaneous T-cell lymphoma; the LymphomADVOCACY award was presented to **Larry Lucchino**, president and CEO of the San Diego Padres and 16-year lymphoma survivor, for his testimony to Congress at a Senate hearing on the blood cancers; and the Together award was presented to the board of directors. . . . **LESALLE LEFALL JR.** received the Cancer Fighter of the Year award from the Beckstrand Cancer Foundation of Long Beach for cancer prevention, treatment and education. LeFall, oncologist, surgeon and Charles R. Drew Professor of Surgery at Howard University College of Medicine, was the first African American president of ACS and the American College of Surgeons and was cancer surgeon to President Reagan. . . . **MOLECULAR CANCER THERAPEUTICS,** a publication of the American Association for Cancer Research, is available online, free of charge until April 15, 2002. The new journal addresses the interrelationship among eight research areas: experimental cancer therapeutics, identification

(Continued to page 8)

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Spiral CT Trial To Enroll 50,000 Former Smokers

(Continued from page 1)

previous version, because it will be more definitive, said project officer John Gohagan, of the NCI Division of Cancer Prevention. The new trial would randomize 50,000 former smokers between the ages of 55-74 to receive either spiral CT or chest x-ray.

"This is an awful lot of money, and I think we're all choking on it," said BSA member William Wood, chairman of the subcommittee that reviewed the NCI proposal. "On the other hand, the impact, if this is a positive study, is incredibly dramatic. This would far exceed coming up with a cure for Hodgkin's disease and melanoma, and probably several other cancers as well, in terms of lives saved.

"We haven't been able to do much over the years for the No. 1 killer of men and women in the U.S. and this offers the potential of making a very significant impact," said Wood, chairman of surgery at Emory University School of Medicine.

In an amendment to the Nov. 14 approval, the board urged NCI to seek partial funding for the trial from other sources such as foundations, insurers, and spiral CT device manufacturers.

"Spiral CT screening may offer a tremendous opportunity to reduce lung cancer deaths," Peter Greenwald, director of NCI's Division of Cancer Prevention, said to the board. "However, the only way to know for sure is through a randomized mortality-endpoint clinical trial. We believe this is one of our best opportunities for reducing cancer deaths."

The trial design provides a 90 percent statistical power to detect progressively smaller mortality effects, starting at a 52 percent mortality reduction in 2005 and dropping to a 20 percent mortality reduction in 2009. The study will recruit investigators and sites that participate in the NCI Lung Screening Study I and the American College of Radiology Imaging Network.

Opportunity Costs

Board members who voted against the trial said they were not convinced that the outcome would justify tying up funds that could be used for other research projects.

"I am opposed to this project because of the lost opportunity cost, because of the uncertainty in the long-term future," said board member Alice Whittemore, chief of epidemiology at Stanford University School of Medicine. "I feel it's a very important problem, and if it could cost a quarter of the money, I would be in favor of it. I'm not opposed scientifically, because I think the study has been put together very well."

Robert Wittes, NCI deputy director for extramural science, said NCI could limit the impact on funding for investigator-initiated research by taking the money from set-aside funds for NCI's targeted grant programs, or Requests for Applications.

"It's fair to say that any project obligating $30 to $50 million a year is going to have an effect on our flexibility," Wittes said to the board. "There would be an immediate dip downward in the [R01 and P01] payline, if that's where we take it. You shouldn't assume that's where it would come from.

"My own bias would be to try to find the funds from other targeted areas of investment rather than to try to find it in the grant pool, because I think we would to the extent possible want to preserve investigator-initiated research," Wittes said. "Realistically, the cost of doing that would be to limit our flexibility in targeted RFAs, for example. It might have an effect on our exceptions funding somewhat. There could be effects elsewhere in the Institute, not necessarily in the intramural line, but somewhere else.

"If you find [the trial] meritorious, even at the price, what we would have to do would be to balance the possible rewards of doing something that actually targets mortality in lung cancer—which is something

THE CANCER LETTER

Member, Newsletter and Electronic Publishers Association

World Wide Web: http://www.cancerletter.com

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Subscription $295 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Founded Dec. 21, 1973, by Jerry D. Boyd

that is actually a proximate good—and I think everybody would agree that we can't equate that with some of the more distant goals so easily, however meritorious they may be," Wittes said. "The reason we are bringing this to you is that we see this as the type of opportunity that doesn't arise very often. So we would have to balance that opportunity on the one hand with the very considerable cost.

"The Institute will feel the effects of this," he said. "On the other hand, our going ahead and articulating that we want to do this is a pretty strong statement of what our values are and what we care about. So if we are targeting the benefit to people of our interventions, then that's a pretty strong selling point for the Institute's programs and our various constituencies out there that we have to come to for support."

The impact of the trial on the Institute's finances will be felt in fiscal 2004, Wittes said.

"Assuming that we—not only the research community but all of the advocacy communities that work with us—could not blunt the flattening of our budget, we would have to fund the study from our existing programs," he said. "I think we would be able to do that. But the cost in damage to other research programs that are ongoing—we haven't done that analysis."

Wood said the trial may not cost the full estimate of $197.6 million if it ends early according to its stopping rules. "If this is clearly coming out a negative trial several years into it, there's no need to pile up an enormous power to a negativity, and if this is as powerful as some of its advocates believe it will be, you could stop early in a positive way," he said.

In either case, the trial will save health care dollars, Wood said.

"If we don't have a clear answer, there will be an increasing drift for the well-insured into demanding this, either paying themselves or getting their insurance to do so, which really takes dollars out of the health care pool," Wood said. "I've lived through that once with bone marrow transplants for breast cancer, which really needed a well-done randomized trial early on, and would have saved an incredible amount of money."

Enlist Insurers?

Board member Gilles McKenna, chairman of radiation oncology, Hospital of the University of Pennsylvania, said hospitals are aggressively marketing spiral CT scanning, causing patients to undergo further expensive and possibly unnecessary medical tests.

"If we don't do this study, it's very possible that this form of cancer screening will become the standard of care," McKenna said. "It is very like the dilemma we faced with bone marrow transplantation in breast cancer, where many women were prepared to undergo this very toxic and, as we now know, harmful therapy, in the hope that it might lead to cure."

McKenna advocated asking insurers to help fund the study. "They stand to benefit no matter how the study comes out," he said.

Barnett Kramer, formerly of NCI, now director of the NIH Office of Medical Applications of Research, said he had presented an earlier version of the study to the Blue Cross/Blue Shield.

"They were extremely interested in the science and really wanted the study to be done, but, this is an organization spread throughout the country, they felt they had no capability to enter into a deal with us," Kramer said. "I don't think we can rely on third-party payers to take this on."

Opportunity Costs Vs. Opportunity

Board members expressed strong opinions for and against the trial.

"I think this may be the greatest opportunity for reducing deaths from cancer that has ever passed this board's hands in the six or seven years I've been on it," said Robert Young, president of Fox Chase Cancer Center. "We can't forget the numbers of deaths per year we're talking about…. One of the opportunity costs that might be lost if we don't fund this trial will be the impact on years of life saved."

The cost of the study has quadrupled "because NCI has been extremely responsive to all of the issues placed before it by this board," Young said. "It is now a well-designed trial with adequate numbers to prove differences that are quite likely based on everything we currently know.

"There is a window of opportunity here," Young said. "[Spiral CT] is going to contribute substantially to health care cost increases and increasing morbidity from inappropriate procedures, all issues this board should be fundamentally interested in. Gilles is right that the health care system ought to have an investment in the resolution in these issues, but based on previous experiences we have had with them in similar situations, it will be somewhere between five and 10 years from now before they get interested in it. They will get interested in it only when it becomes a financial burden to them, and only when it becomes

clear that the courts will not allow them to consistently deny payment for these kinds of screens.

"So, long after all of those who are around this table will be gone from this table, we will be discussing it around this table in 2015. If we don't do it, who will do it? None of the trials planned in Europe are sufficiently size-worthy to really get differences of the type that we suspect might be the case."

Some opponents of the trial argue that spiral CT scanning could distract from smoking cessation efforts.

Young disagrees. "I don't understand that," he said. "In no way does this distract from our strategies in smoking cessation programs. There are now somewhere between 40 and 50 million people in the U.S. who have stopped smoking. They have done everything everyone wanted them to do to reduce their risk. They sit there for 10 or 15 or 20 years, with an increase in risk somewhere between 10 times as much or two times as much. For those 50 million, the application of this tool might be enormously useful."

Nancy Mueller, professor of epidemiology at Harvard School of Public Health, said she did not support the trial. "I think we're only just now beginning to understand how to prevent kids from starting smoking, there's a lot we need to learn about smoking cessation," she said. "We should be looking upstream and not downstream when we have limited resources.

"I don't view the costs listed as the total costs we can expect," Mueller said. "I think it's unlikely to have an early stop to the trial. It will lead to a cascade of questions that will prolong all of this and continue to be a major drain on our budget. I'm more optimistic about alternatives that might be found, biomarkers or more reasonable assays."

Tom Curran, chairman of developmental neurobiology at St. Jude Children's Research Hospital, said he didn't think the study would produce a strongly positive or negative result. "Say everything works as expected, and there is a 50 percent reduction in mortality," he said. "That would be a fantastic result. I haven't yet seen a strong enough scientific rationale to lead me to believe that would be a likely outcome. I'm sure there would be an effect from early detection, but I just don't have a strong feeling of the level of that effect, so I'm not convinced a positive outcome will occur.

"If there is a negative outcome, where we see no effect at all, then we can stop unnecessary treatment of patients and get rid of an attractive technology that we don't need," Curran said. "I'm not convinced that that's likely, either. It's very hard to get a clear negative result in an experiment. I expect the numbers will remain equivocal. My biggest concern is that the outcome will be in the middle ground.

"I'm concerned about setting a precedent with very large trials like this, for which you can always find a justification," Curran said. "I think the small, experimental approaches, which we see on the horizon, some tremendous successes from the kind of smart-bomb targeted development compounds, could suffer if we put a lot of public resources in this direction of very large trials. Scientifically, I just can't feel strong enough about this to support moving this forward."

Herb Kressel, chairman of radiology at Beth Israel Deaconess Medical Center, disagreed.

"The discussion on opportunity costs are interesting, but I think they underestimate the opportunity," Kressel said. "Those of us who deal with lung cancer patients—this is something we could actually do over the next few years that would have this impact. We could have a smart bomb, but no one expects that to have anything like this kind of impact in that amount of time. It's thousands and thousands of lives that could be positively affected by this.

"The upside is so dramatic, that to walk away from it—I can't understand the context of what we view as the mission of the NCI," Kressel said.

Waun Ki Hong, head of cancer medicine at M.D. Anderson Cancer Center, agreed with Kressel.

"The important thing is how can we make an impact in lung cancer," Hong said. "Tom mentioned discoveries of smart bombs, exciting new discoveries. I'd love to see that happen. Lung cancer is a difficult situation. You can make an impact in lung cancer through prevention and early detection. The treatment of metastatic lung cancer, the things we are doing now compared to 20 years ago, we're using different drugs, different radiation techniques and dose, but outcome is the same.

"If you ask me what is the most exciting, promising discovery relevant to lung cancer patients in the last 20 years, my answer is, it's not chemotherapy, it's not targeted therapy, it's not molecular profiles, it's not combined modality treatment, not prevention," Hong said. "I would not hesitate to say that it's spiral CT detecting early lung cancers superior to chest x-ray. That's not a randomized study, only 1,000 patients, and whether or not that finding is related to mortality reduction,

that's not clear. We have an obligation to the public to answer these questions. It's a very solid proposal. In the long term, if the study is positive, it will be very important. We have 40 million former smokers in the country. Once you find early lesions, stage I or stage II, we can cure by surgery about 70 to 80 percent."

David Abrams, director of the Brown University Center for Behavioral and Preventive Medicine, said he supported the trial despite its cost, but was concerned that NCI balance funding between "tobacco science on the upstream and early intervention on the downstream.

"All these tools are needed to have an impact," Abrams said. "We need to do what we need to do to save lives and not pit one area against another."

Richard Schilsky, associate dean for clinical research, University of Chicago, called the trial "the best-designed randomized clinical trial I've ever seen."

"There's no reason to think it won't provide a definitive result," Schilsky said.

Excerpts from the study's concept statement follow:

Spiral CT Lung Cancer Screening Trial. Concept for a new RFP, estimated cost $197.6 million over eight years ($143.6 million to Lung Screening Study and $54 million to American College of Radiology Imaging Network).

During the past three years, staff members in the Division of Cancer Prevention and the Division of Cancer Treatment and Diagnosis have been monitoring progress in observational studies of spiral CT for lung cancer screening. DCP has extensive prior experience carrying out population-based phase III randomized controlled trials of screening technologies and practices with mortality endpoints such as the ongoing Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial that is evaluating the mortality and morbidity impacts of a group of screening tests for four common cancers. In addition, DCP successfully conducted the Lung Screening Study, a pilot study for a large randomized trial of spiral CT. In 1999, DCTD funded a cooperative group of imaging experts, the American College of Radiology Imaging Network, to carry out multi-institutional phase II and III trials of imaging methodologies. In this concept document, an NCI funded trial to evaluate lung cancer screening with spiral CT that would include investigators from PLCO and ACRIN will be proposed.

The search for an efficacious lung cancer screening modality dates back more than 50 years, but as yet no screening modality has been shown in RCTs to reduce lung cancer mortality. Furthermore, screening modalities have attendant harms. The three most influential RCTs were conducted as part of the NCI's Early Lung Cancer Detection Project in the 1970s and 1980s. To trials (Johns Hopkins and Memorial Sloan-Kettering) observed no reduction in lung cancer mortality several regimen of annual chest x-ray and sputum cytology every four months vs. annual chest x-ray alone, indicating that sputum cytology in addition to chest x-ray was not useful. The third trial, the Mayo Lung Project, observed no reduction in lung cancer mortality with chest x-ray and sputum cytology every four months vs. usual care (with participants in the usual care arm receiving only a recommendation at study entry to receive the two tests annually). As no benefit of sputum cytology was observed in the Hopkins and Memorial trials, the results of the MLP were interpreted to indicate that screening chest x-ray does not reduce lung cancer mortality. Over the last 15 years these findings have played a central role in policy decisions concerning lung cancer screening.

However, the MLP had inadequate statistical power to identify a small but clinically important reduction in lung cancer mortality that may be possible with chest x-ray screening. The NCI is currently revisiting this issue in the ongoing PLCO trial. The intervention arm is offered annual chest x-ray, while the control arm continues with its usual care. PLCO was designed for 90 percent statistical power to detect a 20 percent reduction in lung cancer mortality. PLCO randomization concluded in July 2001 at nearly 155,000. Screening will conclude in July 2006.

Low-dose helical computed tomography (helical CT or spiral CT), an advance in CT technology introduced during the 1990s, has been observed to be more sensitive than chest x-ray for identifying lesions in the long. Low-dose spiral CT offers rapid image acquisition at radiation doses substantially below standard high-resolution CT, making it a candidate for lung cancer screening.

The most publicized results regarding the use of low-dose spiral CT as lung cancer screening modality were reported in Lancet in 1999 by the Early Lung Cancer Action Project. ELCAP recruited 1000 volunteers at elevated risk of lung cancer (at least 10 packed years of smoking) and screened them with both chest x-ray and low-dose spiral CT. In this group,

the baseline (prevalence) spiral CT screening detected all non-calcified nodules visible on chest x-ray and also identified other lesions: spiral CT detected non calcified nodules in 233 participants (malignant disease confirmed in 27), while chest x-ray detected non-calcified nodules in only 68 participants (malignant disease confirmed in seven). Additionally, four cancers not characterized as nodules were detected by spiral CT. The findings of ELCAP demonstrate that spiral CT is more sensitive than chest x-ray. But, because the ELCAP incorporates no equivalent control group for comparison, it lacks the ability to determine the impact of spiral CT screening on mortality or to compare potential benefits two harms.

The NCI recognizes the need for further study of spiral CT to determine the mortality reducing efficacy and risks of spiral CT vs. chest x-ray screening for lung cancer. Since early 2000, several workshops devoted to the issue have been held at which the need for an RCT with ample to statistical power to detect a modest reduction in lung cancer mortality was debated and endorsed. The need for an RCT has been discussed extensively in the extramural community as well. There is widespread appreciation that an RCT is needed.

Preliminary data/progress to date: One concern raise during workshop discussions regarding RCTs was whether potential participants would consent to randomization. To assess of the feasibility of conducting an RCT of spiral CT for lung cancer screening, the Lung Screening Study, a 12-month special project within the PLCO trial, was undertaken in September 2000. The goals were to determine the ability to recruit, consent, and randomized to spiral CT vs. chest x-ray high-risk candidates around the nation, measure background use of spiral CT, measure crossover contamination between screening arms, and measure downstream follow-up burden. The target accrual goal was 3000 participants. In just over two months, beginning Sept. 5, 2000, 6 competitively selected PLCO sites and randomized 3373 high-risk participants (PLCO participants were not eligible). Randomized individuals received a single screening spiral CT or chest x-ray. Screening was completed on January 31, 2001. Medical record abstracting was completed by May 31, 2001. Interest in the LSS as was twice as great as projected, and recruitment mailings had to be concluded ahead of schedule. Background use of SCT was very low, less than 2 percent. Compliance with screening examinations was above 90 percent. Crossover contamination from chest x-ray to spiral CT was less than 2 percent. Positivity rates for SCT and CXR were consistent with those observed in ELCAP and PLCO. Detailed results are being prepared for publication in a peer review journal.

Objectives/scope: LSS has demonstrated that interest is great among high-risk individuals, background use of spiral CT in that population is low, randomization at an appropriate rate for a definitive RCT is feasible, and crossover contamination is low.

DCP, which conducts the PLCO trial, has extensive experience carrying out population-based RCTs of a variety of screening tests, and has demonstrated in the LSS project that a spiral CT vs. chest x-ray RCT is feasible at PLCO centers. The standard operating procedures, protocol, and forms developed in the LSS pilot are OMB and IRB approved, field tested, and documented in the LSS Manual of Operations and Procedures. ACRIN began developing a protocol for a randomized trial of spiral CT as part of its original application in 1998. That protocol has been refined and updated during the past three years in response to recommendations from workshops, consensus meetings with thoracic radiologists and oncologists, and comments from review groups. LSS and ACRIN investigators agreed last winter to harmonize their protocols such that data could be combined for evaluating a mortality impact. Representatives from both groups met in Rockville in March 2001, held additional conference calls, and established smaller working groups to pursue specific issues such as definitions of data elements and content of data forms. LSS and ACRIN leaders are confident that data from their respective sites can be combined to evaluate whether a reduction in lung cancer morality exists.

For the NCI Spiral CT Lung Cancer Screening Trial we propose to randomize over a 24-month period approximately 36,000 individuals at competitively selected PLCO centers and 10,000 individuals at participating ACRIN sites, bringing the total enrollment to nearly 50,000 subjects; the 3373 LSS subjects constitute a vanguard group for the trial. All participants will receive an initial screen and two subsequent yearly screens. With yearly analyses of data beginning in March 2005, the NCI Spiral CT Lung Cancer Screening Trial is designed to have 90 percent statistical power to detect progressively smaller mortality effects, and the total cost of the trial will depend on the number of years it takes to detect a significant mortality reduction.

The trial will measure incidence, mortality,

survival, stage, sensitivity, predictive value, harms of screening, diagnostic work-ups, and treatment; cost-effectiveness; and quality of life.

Accrual will begin at up to 10 PLCO sites and approximately 10 ACRIN sites. At the end of year 1, individual site performance and accrual rates will be evaluated. The number of sites and accrual goals at each site then may be adjusted up or down to reach overall study targets in terms of time and budget.

Participants will be offered an initial and two subsequent annual screens. Fifty percent of participants will be randomized to annual spiral CT screening and 50 percent to annual chest x-ray screening. Both study arms will be followed to compare the spectrum of benign and malignant conditions discovered in each. The medical burden of diagnostic work-up and any subsequent therapy will be determined. Follow-up will include ascertainment of adverse medical outcomes, cancer incidence, cause of death, as well as mortality impact.

Every screening center will refer all current smokers randomized into the trial to local smoking cessation programs. Referrals will be made at the initial visit and reinforced at all subsequent visits for participants still smoking and not participating in a smoking cessation program.

Eligibility criteria include ages between 55 and 74 on the date of randomization; a smoking history of at least 30 pack-years, current smokers and former smokers who have quit within 10 years of randomization. Exclusionary criteria include a spiral CT of the lungs or chest in the last 24 months; a known history of lung cancer; currently undergoing treatment for any cancer other than non-melanoma skin cancer; previous removal of any portion of the lung; participation in another cancer screening trial, including PLCO; and participation in a primary cancer prevention trial other than a trial of smoking cessation.

Coordination Centers will work closely with NCI project officers and trial investigators to develop, implement, monitor, and refine the trial protocol. The CCs will be responsible for data management, quality assurance monitoring, and central coordination. NCI will ensure overall coordination of common data sets for analysis.

The trial will have an independent Data and Safety Monitoring Board appointed by the NCI director, composed of organ site experts, technology experts, statisticians expert in clinical trial design and conduct, and consumers to provide external oversight for all aspects of the trial.

NCI Seeks Nominations For Consumer Liaison Group

NCI is seeking nominations for five new members of the NCI Director's Consumer Liaison Group, to be appointed in July 2002.

The DCLG helps NCI to identify appropriate advocates to serve on its program and policy advisory committees, and it serves as a channel for consumer advocates to voice their views and concerns.

The DCLG is a federal chartered advisory committee. It consists of 15 consumer advocates who are involved in cancer advocacy and who reflect the diversity among those whose lives are affected by cancer.

NCI brings together these advocates from many communities to advise and make recommendations to the NCI director, from the consumer advocate perspective on a wide variety of issues, programs and research priorities. All DCLG members must be U.S. citizens.

NCI encourages nomination of candidates reflecting the diversity sought on the DCLG. Nominations can be made by organizations, including local/regional and national groups, or individuals, including self-nominations.

To receive a nomination package for the DCLG, send name, advocacy/voluntary organization affiliation (if any), address and phone number to Liaison Activities, NCI, c/o Palladian Partners, 1010 Wayne Avenue, Suite 1200, Silver Spring, MD 20910, fax 301-650-8676, or go to http://www.nci.nih.gov/partners/liaisonrequest.html and complete the electronic form. Nominations must be postmarked by February 1, 2002.

FDA Seeks Consumers For Advisory Committees

FDA is seeking people with strong ties to consumer and community-based organizations to serve as consumer representatives on its advisory committees.

Consumer reps are included on all advisory committees, which provide FDA with independent opinions and recommendations from outside experts on regulated products and Agency policies.

For further information on becoming a consumer representative, visit http://www.fda.gov/oc/advisory/default.htm or contact FDA's Office of Consumer Affairs at 301-827-5006.

Funding Opportunities:

Mucio Athayde Cancer Prize Open For Nominations

Mucio Athayde Cancer Prize 2002

Nominations Receipt Deadline: Before Dec. 31, 2001

The 5th annual award will be presented for a major discovery or significant contribution with global impact in basic research, clinical investigation or cancer control and epidemiology, carried out within the last ten years.

The $100,000 cash award will be presented by the International Union Against Cancer (UICC) in Oslo June 28, 2002.

Information is available at the following Web site: http://www.uicc.org.

Inquiries: Send nominations marked "confidential" to Secretariat of the Selection Committee, c/o executive director, UICC, 3 Rue de Conseil-General , Switzerland, phone 41-22-809-1811; fax 41 22 809 1810; e-mail info@uicc.org.

RFA Available

RFA-CA-02-011: Early Clinical Trials of New Anti-Cancer Agents with Phase I Emphasis

Letter of Intent Receipt Date: Feb. 14, 2002

Application Receipt Date: March 21, 2002

The RFA would provide funding to assess novel agents available through NCI in early clinical, dose finding trials.

The objective is to establish safe and biologically active treatment schedules for patients with cancer and to establish proof of principle for new agents directed at novel molecular targets. Most of these trials will include pharmacokinetic assessment. Many will include assessment of drug exposure and effect.

Investigators and support staff will form teams to propose, develop, perform and analyze the results of early trials. The teams should include clinical investigators with expertise in the performance of early clinical trials, collaborating with researchers with expertise in clinical pharmacology and translational correlative studies as well as support staff.

Single institution phase I studies are preferred, although laboratory studies may be conducted with collaborators at other institutions.

Strong justification, evidence of well-established collaborations and clearly described procedures must be supplied for multi-institutional applications. The administrative and funding instrument will be a cooperative agreement U01, an assistance mechanism. The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-02-011.html.

Inquiries: Louise Grochow, chief, Investigational Drug Branch , Cancer Therapy Evaluation Program , Division of Cancer Treatment and Diagnosis, NCI, Executive Plaza North, Rm 7131, 6130 Executive Blvd., MSC 7426, Bethesda, MD 20892-7432, phone 301-496-1196; fax 301-402-0428; email grochowl@ctep.nci.nih.gov.

In Brief:

New AACR Journal Available Free Online Until April 15

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of molecular targets, targets for chemoprevention, new models, cancer chemistry and drug discovery, molecular and cellular pharmacology, molecular classification of tumors, and bioinformatics and computational molecular biology. **Daniel Von Hoff**, director of the Arizona Cancer Center, is editor-in-chief of the journal. It is available at the following Web site: http://mct.aacrjournals.org . . . . **PRODUCE FOR BETTER HEALTH FOUNDATION** has begun a $6 million fund raising campaign to expand the reach of the 5 A Day program, the foundation's initiative to encourage five to nine daily servings of fruit and vegetables. The funds will be used to form new partnerships and develop improved strategic communication, the foundation said. The foundation said it has received gifts of $1.762 million from produce companies and suppliers. The foundation is celebrating the 10th anniversary of 5 A Day, which began in 1991 as a partnership between the foundation and NCI. The program completed a tour of the Northeastern U.S. with its "Produce Man" costumed character visiting schools and grocery stores. . . . **WILLIAM PETROS** was appointed associate director for anti-cancer drug development at the Mary Babb Randolph Cancer Center at West Virginia University. Petros, known for his work in pharmacometrics, was director of the Pharmaceutical Research Resource for the Duke University Cancer Center and faculty member in the Duke University Department of Medicine for 11 years. . . . **CORRECTION:** In an item in the In Brief section of **The Cancer Letter** on Nov. 9, the PNC Foundation was incorrectly identified.

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